REMARKS

Claims 1-3, 5, 7-16, 18, 19, 21-25, and 27-31 are pending in this application. Claims 1, 14, 19, and 23 are amended to further clarify the subject matter, as explained in the Interview Summary below.

INTERVIEW SUMMARY

Applicants thank Examiners Flory and Manuel for the courtesy and assistance provided in the personal interview on 13 June 2008. Applicants submit this Statement of Substance of Interview to summarize the interview in compliance with MPEP § 713.04.

Type of Interview: In-person

Names of Participants: Christopher Flory, George Manuel, Steven Yu

Exhibits: N/A

Claims Discussed: All the pending claims.

References Discussed: All references presently cited against the claims.

Principal Arguments of Applicant: The arguments already made of record were presented.

Agreement: Applicants agreed to the Examiners' suggestion to clarify that the engagable association of the leading delivery contact and the trailing delivery contact for each of the series of flexibly connected delivery contacts is independent of any other series of flexibly connected delivery contacts (claim 1) and to clarify that the probe, terminal member, or delivery structure can be re-positioned on the shaft (claims 14, 19, and 23).

REJECTIONS UNDER § 103

Claims 1-3, 5, 7-13, 15, 19, 21-25, and 27-31 are rejected under § 103(a) as allegedly being unpatentable over Kieval (U.S. Patent No. 6,178,349), which incorporates by reference therein Testerman et al. (U.S. Patent No. 5,344,438). Applicants respectfully request reconsideration of this rejection.

Regarding claims 1, 14, 19, and 23, the Office Action asserts that the terms "delivery contacts," "probe," "terminal member," and "clamping members," all substantially define the same or substantially similar structures. Applicants respectfully disagree. According to the MPEP § 2111, the claim terms should be construed in light of the specification. As used throughout the specification, these terms do not necessarily refer to the same or similar structures. For example, a "delivery contact" is represented by reference number 20 in the embodiment shown in FIG. 1; a "probe" is represented by reference number 210 in the embodiment shown in FIG. 14; a "terminal member" is represented by reference number 280 in the embodiment shown in FIG. 17; and "clamping member" is represented by reference number 242 in the embodiment shown in FIG. 16. As seen in these examples (when the claims are read in light of the specification), the terms "delivery contacts," "probe," "terminal member," and "clamping members" do not necessarily define the same or substantially similar structures.

Independent claim 1 recites a delivery device comprising a first, second, and third series of flexibly connected delivery contacts, wherein "the first series of flexibly connected delivery contacts has a first diameter, the second series of flexibly connected delivery contacts has a second diameter, and the third series of flexibly connected delivery contacts has a third diameter, the third diameter being greater than the first diameter and the third diameter being greater than the second diameter in an operative position of the device."

Regarding claim 1, the Office Action concedes that Kieval does not expressly disclose that the third diameter is greater than the first or second diameters. The Office Action further asserts that this particular feature does not provide any advantage, have a particular purpose, or solves a stated problem, and as such, having the third diameter be greater than the first diameter and second diameter would have been an obvious matter of design choice.

Applicants respectfully disagree and point out that having the third diameter be greater than the first diameter and second diameter allows the delivery contacts to better conform to the anatomical structure of a ganglion. For example, referring to the embodiment shown in FIG. 4 of the specification, delivery device 10 has three series of flexibly connected delivery contacts: a first series (top), a second series (bottom), and a third series (middle).[1] The third series has a

[1] Specification, pg. 7, lns. 21-32.

larger diameter than the first series and second series. This allows device 10 to form "a substantially ovoid configuration to conform to the configuration of a ganglion."[2] As such, this feature has a particular purpose and would not have been a mere matter of design choice.

Claim 5 recites three series of flexibly connected delivery contacts, with each series having four delivery contacts. For example, referring to the embodiment shown in FIG. 13, device 10a has three series of flexibly connected delivery contacts, each with four delivery contacts (20a-20d). As explained in the specification,[3] the number of delivery contacts in each series can depend upon characteristics of the ganglion to be stimulated, which in turn relates to characteristics of the patient (e.g., age, height, or gender) as well as the type of ganglion. A device having three series of flexibly connected delivery contacts, with each series having four delivery contacts, is particularly useful in certain patients and/or certain ganglia.

Regarding claim 5, the Office Action asserts that the reservoir in Kieval represents a delivery contact. Applicants respectfully disagree. The Office Action omits any explanation of how the reservoir in Kieval has the structure or function of a delivery contact. Without a clear articulation of the reasons for the rejection, the Office Action fails to make a *prima facie* case for obviousness.

Alternatively, the Office Action concedes that Kieval does not expressly disclose four electrodes, but that it would have been routine to duplicate essential working parts. Applicants respectfully disagree. As explained in the specification, the number of delivery contacts in each series can depend upon characteristics of the ganglion to be stimulated, which in turn relates to characteristics of the patient (e.g., age, height, or gender) as well as the type of ganglion.[4] A device having three series of flexibly connected delivery contacts, with each series having four delivery contacts, is particularly useful in certain patients and/or certain ganglia. As such, having four delivery contacts is not a mere duplication of working parts.

Claim 10 recites delivery contacts having a trapezoidal configuration. Regarding claim 10, the Office Action asserts that the electrode and reservoir in Figs. 3 and 4 of Kieval are trapezoidal, or alternatively, that Testerman discloses trapezoidal contacts in col. 2, lns. 39-45.

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[2] Specification, pg. 7, lns. 23-24.
[3] Specification, pg. 8, ln. 29 – pg. 9, ln. 17.
[4] Specification, pg. 8, ln. 29 – pg. 9, ln. 17.

Applicants respectfully disagree. In Kieval, neither the electrode (#132 in Fig. 3 and #156 in Fig. 4) nor the reservoir (#134 in Fig. 4 and #154 in Fig. 4) are trapezoidal. In Testerman, the passage referred to by the Office Action indicates that the strips of metal are rectangular, not trapezoidal.

Claims 12, 14, 19, and 23 recite an axially elongated shaft and a device, probe, terminal member, or delivery structure that is slidably engagable therewith. Regarding claims 12, 14, 19, and 23, the Office Action asserts that leads 96 and 98 in Kieval represent an axially elongated shaft. The Office Action further states: "The shaft is considered slidably engagable with the device because the suture means (Fig. 2, left of reference 94) is slidable along the lead to secure the cuff. Additionally, the cuff is slidable or positionable along the nerve." Applicants respectfully disagree with this analysis. The Office Action does not make clear how the suture means being slidable along the lead or how the cuff being slidable along the nerve relates to the features recited in the claims. Is the Office Action suggesting that the cuff is slidable along the lead? If so, this is indicated nowhere in Kieval. Without a clear articulation of the reasons for the rejection, the Office Action fails to make a *prima facie* case for obviousness.

Also, the Office Action asserts that the leads in Kieval are inherently slidably engaged with the nerve cuffs because "the lead housing must be inserted with the nerve cuff in the construction of the device." Applicants respectfully disagree. First, it is not necessary that the lead housing in Kieval must be inserted with [sic] the nerve cuff during construction. The cuff in Kieval may simply be attached to the end of the lead. In any case, there is no indication in Kieval of how the nerve cuff and lead interact during construction. Second, even if the lead were inserted into the nerve cuff, this does not necessarily mean that the nerve cuff is slidable along the lead. It is common for electrodes to be fixed on a lead, rather than being slidable along a lead. In fact, in many instances, allowing the electrode to slide along the lead is undesirable (especially where precise electrode positioning is required, such as deep brain stimulation). In any case, there is no indication anywhere in Kieval that the nerve cuff is slidable along the lead.

Claim 27 recites that a first and second "pair of connected clamping members are hingedly connected to each other." Regarding claim 27, the Office Action asserts that each front flat edge of nerve cuff 112 in Kieval represents a clamping member that are hingedly connected

to each other by the its flexible portion. Applicants respectfully disagree. The edges of nerve cuff 112 do not have a configuration where the two edges "mutually confront each other."[5]

Alternatively, the Office Action asserts that each of nerve cuffs 92 and 94 in Fig. 1 of Kieval represent a clamping member. Applicants respectfully disagree. Each of nerve cuffs 92 and 94 are separated from each other – they are not hingedly connected to each other, as required by claim 27.

Claim 29 recites that the delivery device maintains an ovoid shape in an operative position of the device. Regarding claim 29, the Office Action asserts that the semi-circular nerve cuff in Kieval has a substantially ovoid shape. Applicants respectfully disagree. A semi-circular shape is not even a complete circular shape, much less an ovoid shape.

Claims 30 and 31 recite slidably engaging a ganglion stimulator with an axially elongated shaft. Regarding claims 30 and 31, the Office Action asserts that the stimulator and shaft in Kieval are considered slidably engagable for the reasons stated in regards to claim 12. For the same reasons explained above, Applicants respectfully disagree. The Office Action does not clearly indicate what structure in Kieval is the stimulator, what structure is the shaft, and how they are slidably engagable with each other. Without a clear articulation of the reasons for the rejection, the Office Action fails to make a *prima facie* case for obviousness.

Claims 14, 16, and 18 are rejected under § 103(a) as allegedly being rendered obvious by Kieval alone, or alternatively, by Kieval in view of Levin et al. (US 2005/0234523) or Shafer (US 2005/0075701). Applicants respectfully request reconsideration of this rejection.

Independent claim 14 recites an assembly for stimulating ganglia comprising a "first probe having one or more prongs for insertion in a ganglion" and a "second probe having one or more prongs for insertion in a ganglion." For example, referring to the embodiment shown in FIG. 14, neurostimulation assembly 200 has a first probe 210a and a second probe 210b that have prongs for insertion into a ganglion.[6] In another example, referring to the embodiment

[5] Specification, pg. 13, lns. 25-29.
[6] Specification, pg. 12, lns. 15-30.

shown in FIG. 15, a neurostimulation assembly has a first probe 210 with dual prongs 210a' and 210a''; and a second probe 210b with dual prongs 210b' and 210b''.[7]

In regards to claim 14, the Office Action asserts that the terms "delivery contacts," "probe," "terminal member," and "clamping members," all substantially define the same or substantially similar structures. Applicants respectfully disagree for the reasons explained above.

Further in regards to claim 14, the Office Action asserts that the device of Kieval is capable of being inserted into a ganglion. Applicants respectfully disagree. Fig. 2 in Kieval shows nerve stimulator 92 being positioned on the external surface of nerve 64. There is nothing in the disclosure of Kieval or the structure of nerve stimulator 92 that suggests that nerve stimulator 92 could be inserted into a ganglion. In contrast, Kieval states that "the base 118 [of nerve stimulator 92] assumes a cuff configuration so as to be wrapped about the nerve 46" (col. 5, lns. 49-50). Thus, nerve stimulator 92 is designed specifically to be wrapped around a nerve and does not have any type of structure that would allow it to penetrate into a ganglion.

Also, Applicants respectfully submit that there is nothing wrong with defining some part of an invention in functional terms. According to the MPEP § 2173.05: "A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step." Consistent with this MPEP guideline, Claim 14 recites "prongs" and defines the capability of the "prongs."

Further regarding claim 14, the Office Action asserts that leads 96 and 98 in Fig. 1 of Kieval is an axially elongated shaft, and that the "shaft is considered slidably engagable with the device because the suture means (Fig. 2, left of reference 94) is slidable along the lead to secure the cuff. Additionally, the cuff is slidable or positionable along the nerve." As explained above, the Office Action does not make clear how the suture means being slidable along the lead or how the cuff being slidable along the nerve relates to the features recited in the claims. Without a clear articulation of the reasons for the rejection, the Office Action fails to make a *prima facie* case for obviousness.

Also, the Office Action asserts that the leads in Kieval are inherently slidably engaged with the nerve cuffs because "the lead housing must be inserted with the nerve cuff in the construction of the device." Applicants respectfully disagree for the reasons explained above.

[7] Specification, pg. 12, lns. 28-30.

Claim 16 recites that "the first probe has two prongs and the second probe has two prongs." In regards to claim 16, the Office Action asserts that the first and second probes in Kieval are considered to represent a first prong and second prong. Applicants respectfully point out that claim 16 does not recite a first prong and second prong. Rather, claim 16 recites that "the first probe has two prongs and the second probe has two prongs." For example, referring to the embodiment shown in FIG. 15, a neurostimulation assembly has a first probe 210 with dual prongs 210a' and 210a"; and a second probe 210b with dual prongs 210b' and 210b".[8]

Alternatively, the Office Action asserts that the leading edges of the probes in Kieval can be considered a prong capable of insertion into a ganglion. For the reasons explained above, Applicants respectfully disagree that the probes in Kieval are capable of insertion into a ganglion.

Alternatively, the Office Action asserts that Kieval can be combined with the barb or screw taught in Levin at ¶¶ [0092] and [0111]. Applicants respectfully disagree as there is no motivation to combine the references. In ¶ [0092], Levin states: "The tip 308 is then brought into the electric contact with the wall of the vein 304. Hooks or screws, similar to ones used to secure pacemaker leads, can be used to anchor the tip and improve the electric contact." In ¶ [0111], Levin states: "Stimulation catheter or lead 903 is introduced into the renal vein 902 and anchored to the wall of the vein using a securing device 904. The securing device can be a barb or a screw if the permanent placement of the lead 903 is desired." Thus, the passages in Levin referred to by the Office Action disclose hooks, barbs, or screws for anchoring to the wall of a vein, not for insertion into a ganglion. As such, there is no reason for combining the nerve stimulator of Kieval with the vein wall anchoring structures of Levin.

The Office Action also asserts that the device in Kieval can be combined with the tined lead anchors of Shafer. Applicants respectfully disagree that Kieval can properly be combined with Shafer. However, even if this combination was proper, the combination still fails to have all the elements of claim 14, which requires that the first and second probes be "slidably engagable with the outer surface of the shaft." As explained above, the nerve stimulator in

[8] Specification, pg. 12, lns. 28-30.

Kieval is not slidable along the lead. Shafer fails to correct this deficiency in Kieval, and therefore, the combination of Kieval and Shafer would not arrive at the invention of claim 14.

For at least the above-stated reasons, Applicants respectfully submit that the pending claims in this application are patentable over the cited references. Accordingly, withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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